REMARKS

The present response is intended to be fully responsive to the objections and rejections raised in the Office Action, and is believed to place the application in condition for allowance. Further, the Applicants do not acquiesce to any portion of the Office Action not particularly addressed. Favorable reconsideration and allowance of the application is respectfully requested.

As of the mailing of the present Office Action, claims 1-9 were pending in the application, including original claims 1-5 and 7, and as-amended claims 6, 8 and 9 (original claims 6, 8 and 9 having been amended by means of a Preliminary Amendment filed August 29, 2006). In the Office Action, the Examiner noted that:

1) the drawings of the application filed on January 17, 2006 are accepted;

2) acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f), with respect to which, all copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau pursuant to PCT Rule 17.2(a);

3) the U.S., Foreign and Other document citations presented by the Applicants via the Information Disclosure Statement paper mailed January 17, 2006 have been considered, as indicated by the placement of the Examiner's initials beside each such document citation in an attached copy of the corresponding Form PTO-1449;

4) the oath or declaration is defective, and a new oath or declaration is required;

5) claims 1-9 are rejected as allegedly failing to comply with the enablement requirement set forth in 35 U.S.C. §112, first paragraph;

6) claims 5, 8 and 9 are rejected as being allegedly indefinite under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

7) claims 1-9 are rejected under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter;

8) claims 1, 2 and 6 are rejected as being allegedly anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 3,240,207 to Barker, *et al.* (*Barker*);

9) claims 3-4 are rejected as being allegedly obvious under 35 U.S.C. §103(a) over *Barker* in view of U.S. Patent No. 5,807,258 to Cimochowski, *et al.* (*Cimochowski*); and

10) claims 5 and 7-9 are rejected as being allegedly obvious under 35 U.S.C. §103(a) over *Barker* in view of U.S. Patent No. 5,693,091 to Larson, Jr. *et al.* (*Larson*).

By this response, claim 2 is canceled, claims 1 and 3-9 are amended to more clearly recite the subject matter of the application, and each of new claims 10-26 is added, such that the pending claims are now claims 1 and 3-26. Of the pending claims 1 and 3-26, each of claims 1, 13 and 24 is presented in independent form. No new matter has been added to the application. In view of the above amendments and the following discussion, the Applicants submit that each of the claims now pending in the application is directed to statutory subject matter under the provisions of 35 U.S.C. §101 and complies with the enablement requirement set forth in the first paragraph of 35 U.S.C. §112, and that none of the claims now pending in the application is indefinite under the provisions of the second paragraph of 35 U.S.C. §112, anticipated under the provisions of 35 U.S.C. §102, or obvious under the provisions of 35 U.S.C. §103. Thus, the Applicants believe that each of the claims now pending in the application is in condition for allowance.

I. ACCEPTANCE OF DRAWINGS, ACKNOWLEDGEMENT OF CLAIM FOR FOREIGN PRIORITY, CONSIDERATION OF APPLICANT-CITED DOCUMENTS

The Examiner stated that the drawings received on January 17, 2006 are accepted, indicated that the Applicants' claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) is acknowledged, and further indicated (via the placement of Examiner's initials on the corresponding Form PTO-1449) that each the U.S., Foreign and Other documents cited by the Applicants via the Information Disclosure Statement paper mailed January 17, 2006 have been considered. The Applicants appreciate and thank the Examiner for promptly accepting the drawings, acknowledging the foreign priority claim, and duly indicating that the cited documents have been considered.

II. OATH OR DECLARATION CONSIDERED DEFECTIVE, NEW OATH OR DECLARATION REQUIRED

The Examiner stated that the oath or declaration filed on May 18, 2006 in response to the Notification of Missing Requirements under 35 U.S.C. §371 mailed May 5, 2006 is defective because non-initialed and/or non-dated alterations have allegedly been made to it, and that a new oath or declaration is required in compliance with 37 C.F.R. 1.67(a) identifying the present application by application number and filing date. In response, the Applicants respectfully draw the Examiner's attention to a new Declaration duly executed by the inventors, and identifying the present application by application number and filing date in accordance with 37 C.F.R. 1.67(a). Accordingly, the Applicants request prompt acknowledgement from the Examiner that the attached new Declaration has been received and deemed acceptable.

III. CLAIM AMENDMENTS

The Applicants have canceled claim 2, and amended each of claims 1 and 3-9 to more precisely define the presently claimed subject matter. In particular, claim 1, directed to an implantable device, has been amended to recite, *inter alia*, "an implantable cannula adapted to connect the heart of a patient to a blood pump" and "a

cuff with at least one pressure sensor encapsulated therein, wherein said at least one pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through said cannula from said heart to said pump". Support for such amendment to claim 1, as well as support for the amendments to claims 3-9, is found in the application, as filed (see, *e.g.*, line 18 of page 8 of the as-filed specification; lines 1-4 and 18-19 of page 9 the as-filed specification; page 10, lines 22-24 of the as-filed specification; page 15, line 14 to page 18, line 24 of the as-filed specification; as-filed FIGS. 1, 2, 5, 6, 7 and 8; as-filed claims 1-2).

New claims 10-26 find support in the specification, as filed (see, *e.g.*, line 18 of page 8 of the as-filed specification; lines 1-4 and 18-19 of page 9 the as-filed specification; page 10, lines 22-24 of the as-filed specification; page 15, line 14 to page 18, line 24 of the as-filed specification; as-filed FIGS. 1, 2, 5, 6, 7 and 8; as-filed claims 1-9).

For at least the foregoing reasons, applicants respectfully submit that the proposed claim amendments do not raise issues of new matter. Prompt entry thereof is respectfully requested.

IV. REJECTION OF CLAIMS 1-9 UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner rejected claims 1-9 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. In this regard, the Examiner indicates that claim 1 recites that the cuff is positioned to contact the outer surface of a tubular body and that the cuff is integrally formed within a cannula. In response, the Applicants direct the Examiner's attention to claim 1, as amended, in which the "positioned to contact the outer surface of a tubular body" recitation has been removed. In such circumstances, the Applicants respectfully suggest that the concern giving rise to the present rejection has been eliminated. Accordingly, the Applicants respectfully request that the rejection be withdrawn as moot.

V. REJECTION OF CLAIMS 5, 8 AND 9 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner rejected claims 5, 8 and 9 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which the Applicants regard as the invention. In this regard, the Examiner indicates that claim 5 recites the limitation "said heart", claim 8 recites the limitation "said blood pump", and claim 9 recites the limitation "said implantable blood pump", each of which is said to have insufficient antecedent basis in the dependent claim or in the intervening dependent claims. In response, the Applicants direct the Examiner's attention to claim 1, as amended, in which is recited "heart of a patient" and "blood pump", providing antecedent basis to corresponding limitations set forth in claims 5, 8 and 9. In such circumstances, the Applicants respectfully suggest that the concerns giving rise to the present rejection have been eliminated. Accordingly, the Applicants respectfully request that the rejection be withdrawn as moot.

VI. REJECTION OF CLAIMS 1-9 UNDER 35 U.S.C. §101

The Examiner rejected claims 1-9 under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter. In this regard, the Examiner indicates that claim 1 recites that "a cuff positioned to contact the outer surface of a tubular body". In response, the Applicants direct the Examiner's attention to claim 1, as amended, in which the "a cuff positioned to contact the outer surface of a tubular body" recitation has been removed. In such circumstances, the Applicants respectfully suggest that the concern giving rise to the present rejection has been eliminated. Accordingly, the Applicants respectfully request that the rejection be withdrawn as moot.

VII. REJECTION OF CLAIMS 1, 2 and 6 UNDER 35 U.S.C. §102(b)

The Examiner rejected claims 1-4, 7 and 8 as being allegedly anticipated by *Barker*. In particular, with respect to claim 1, the Examiner stated that *Barker*

> Teaches an implantable device (FIG. 3 of Barker), including: a cuff (flexible tube 10 of Barker) positioned to contact the outer surface (8 in FIG. 3 of Barker) of a tubular body (artery 7 of Barker) which measures blood pressure encapsulated within said cuff (Col. 3, lines 41-70 of Barker), wherein said cuff is integrally formed within a cannula (rigid ring 11, FIG. 1 of Barker). As it is shown in FIGS. 1-3 the cuff does not substantially occlude or affect the flow of blood within the artery.

The rejection is respectfully traversed.

Barker generally teaches a blood pressure sensor for implanting in a living body. (*Barker*, Col. 1, lines 9-11) In particular, *Barker* teaches a metal ring 11 in which is formed a radial hole, and a pressure transducer 13 inserted within the radial hole in the metal ring such that a pressure sensitive portion thereof is in contact with the exterior of a resilient tube of an arterial graft. (Barker, Col. 3, lines 41-45)

Barker, however, does not teach each and every element of the Applicants' invention recited in any of the presently pending claims. For example, independent claim 1, directed to an implantable device comprising: an implantable cannula adapted to connect the heart of a patient to a blood pump, and a cuff with at least one pressure sensor encapsulated therein, wherein said at least one pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through said cannula from said heart to said pump.

Barker, by contrast, fails to teach or suggest either of an implantable cannula "adapted to connect the heart of a patient to a blood pump", or a cuff with at least one pressure sensor "encapsulated therein", as required by claim 1. For example, to the extent *Barker* discloses a tube of an arterial graft, the same is not adapted in any way to connect to a blood pump. For another example, to the extent Barker discloses a cuff with a pressure sensor, the latter cannot fairly be described as being encapsulated in the former.

"Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Since *Barker* fails to teach or suggest either of an implantable cannula "adapted to connect the heart of a patient to a blood pump", or a cuff with at least one pressure sensor "encapsulated therein", as required by claim 1, *Barker* does

not teach each and every element of the Applicants' invention recited in independent claim 1.

Accordingly, the Applicants contend that claim 1 is patentable over *Barker*, and respectfully requests withdrawal of the present rejection under Section 102(b). The Applicants further respectfully submit that the implantable device of independent claim 1 provides patentably distinct advantages with respect to facilitating the incorporation of sensors in a device that includes a cannula to facilitate the detection of pressure of blood flowing within the cannula, at least insofar as the sensors are encapsulated within a cuff which may be positioned with respect to the cannula in different ways with relative ease (e.g., positioned on the cannula, around the cannula, or integrally formed within a body portion of the cannula), that translate into manufacturing options, advantages and efficiencies that are not achieved and/or achievable with the apparatus of *Barker*. For at least this additional reason, the Applicants submit that independent claim 1 presented herein is patentable over all art of record, including specifically *Barker*.

Claims 2-9 depend, either directly or indirectly, from claim 1, and recite additional features therefor. At least since *Barker* does not anticipate the Applicants' invention recited in claim 1, *Barker* also fails to anticipate the Applicants' invention recited in any of claims 2-9. Moreover, the Applicants submit that the devices of each of claims 2-9 provide patentably distinct advantages with respect to facilitating the incorporation of sensors in a device that includes a cannula to facilitate the detection of pressure of blood flowing within the cannula, at least insofar as the sensors are encapsulated within a cuff which may be positioned with respect to the cannula in different ways with relative ease (e.g., positioned on the cannula, around the cannula, or integrally formed within a body portion of the cannula), that translate into manufacturing options, advantages and efficiencies that are not achieved and/or achievable with the apparatus of *Barker*. Accordingly, the Applicants contend that each of claims 2-9 is patentable over *Barker* The Applicants respectfully request withdrawal of the present rejections of claims 2-9.

VIII. REJECTION OF CLAIMS 3-4 UNDER 35 U.S.C. §103(a)

The Examiner rejected claims 3-4 as being allegedly obvious over *Barker* in view of *Cimochowski*. In particular, the Examiner cites *Cimochowski* for teachings regarding

ultrasonic sensors (242a, 242b in FIG. 20A of *Cimochowski*) for monitoring the pressure through a vascular graft, wherein the pressure sensor can be aligned axially (transducers 242a and 242b in FIG. 20A) or on opposite sides of the graft (transducers 174a and 174b in FIG. 14). The rejection is respectfully traversed.

As the Examiner is aware, to establish a *prima facie* case of obviousness, one of the basic criteria that must be met is that the prior art reference (or references when combined) must teach or suggest all the claimed limitations. *In re* Vaeck, 947 F. 2d, 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Here, a *prima facie* case of obviousness has not been established, at least because each of independent claim 1, from which each of claims 3 and 4 depends, recites limitations not taught nor suggested in either of *Barker* or *Cimochowski*, whether taken alone or in combination.

The patentability of claim 1 over *Barker* has been discussed above. The Examiner cites *Cimochowski* to teach axially- and radially-aligned sensors. *Cimochowski*, however, apparently fails, *inter alia*, to teach or suggest a modification to the teachings of *Barker* that would yield an implantable cannula: 1) adapted to connect the heart of a patient to a blood pump, or 2) a cuff with at least one pressure sensor encapsulated therein wherein said at least one pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through said cannula from said heart to said pump, as required by claim 1. As such, a *prima facie* case of obviousness has not been established because the combination of the cited references fails to yield all of the limitations recited in the independent base claim.

Thus, the Applicants respectfully submit that each of claims 3 and 4 is patentable over *Barker* in view of *Cimochowski*. The Applicants respectfully request that the rejection be withdrawn and the claims allowed.

IX. REJECTION OF CLAIMS 5 and 7-9 UNDER 35 U.S.C. §103(a)

The Examiner rejected claims 3-4 as being allegedly obvious over *Barker* in view of *Larson*. In particular, the Examiner cites *Larson* for teachings regarding the use of a controller as part of a feedback mechanism. The rejection is respectfully traversed.

To repeat, to establish a *prima facie* case of obviousness, one of the basic criteria that must be met is that the prior art reference (or references when combined)

must teach or suggest all the claimed limitations. *In re* Vaeck, 947 F. 2d, 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Here, a *prima facie* case of obviousness has not been established, at least because each of independent claim 1, from which each of claims 5 and 7-9 depends, recites limitations not taught nor suggested in either of *Barker* or *Larson*, whether taken alone or in combination.

The patentability of claim 1 over *Barker* has been discussed above. The Examiner cites *Larson* to teach the use of a controller as part of a feedback mechanism. *Larson*, however, apparently fails, *inter alia*, to teach or suggest a modification to the teachings of *Barker* that would yield an implantable cannula: 1) adapted to connect the heart of a patient to a blood pump, or 2) a cuff with at least one pressure sensor encapsulated therein wherein said at least one pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through said cannula from said heart to said pump, as required by claim 1. As such, a *prima facie* case of obviousness has not been established because the combination of the cited references fails to yield all of the limitations recited in the independent base claim.

Thus, the Applicants respectfully submit that each of claims 5 and 7-9 is patentable over *Barker* in view of *Larson*. The Applicants respectfully request that the rejection be withdrawn and the claims allowed.

X. NEW CLAIMS 10-26 ALSO ALLOWABLE

Applicants respectfully direct the Examiner's attention to the above-noted claim amendments, by which new claims 10-26 are added to the pending claims. More particularly, the Applicants respectfully urge that each of claims 10-26 is patentable over all of the prior art of record, including particularly over each of *Barker*, *Cimochowski* and *Larson*, whether considered singly or in combination thereof, for at least the reasons each of claims 1-9 is patentable thereover, including because the prior art of record fails to teach or suggest any of:

A) an implantable device, comprising: an implantable cannula adapted to connect the heart of a patient to a blood pump, and a cuff with at least one pressure sensor encapsulated therein, wherein said at least one pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through said cannula

from said heart to said pump, as required by claim 1, and by dependency therefrom, by claims 10 and 11;

B) an implantable device, comprising an implantable cannula adapted to connect the heart of a patient to a blood pump, and a thin walled substantially tubular member with at least one pressure sensor encapsulated therein, wherein said at least one pressure sensor is positioned and adapted to non-invasively detect the pressure of blood flowing through said cannula from said heart to said pump, as required by independent claim 13, and by dependency therefrom, by claims 14-22; or

C) an implantable device, the device comprising, in combination, 1) a cannula adapted to connect the heart of a patient to a blood pump, said cannula including a body portion for carrying blood from the former to the latter, said body portion including interior walls defining a tubular passage extending through the cannula, and 2) a pressure sensing member, the pressure sensing member including a thin walled, substantially tubular body and at least one pressure sensor embedded in the thin walled, substantially tubular body, wherein the thin walled, substantially tubular body of the pressure sensing member is positioned with respect to the body portion of the cannula such that the at least one pressure sensor embedded therein is operable to non-invasively detect a liquid pressure of blood flowing through the tubular passage, as required by independent claim 23, and by dependency therefrom, by claims 24-26.

Prompt allowance of new independent claims 13 and 23, and of new dependent claims 10-11, 14-22 and 24-26, is respectfully requested.

CONCLUSION

In view of the foregoing, the Applicants submit that each of the claims now pending in the application is presently in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issue are earnestly solicited.

If, however, the Office believes that any unresolved issues still exist or if, in the opinion of the Office, a telephone conference would expedite passing the present application to issue, the Office is invited to call the undersigned attorney directly at 203-399-5928 or the office of the undersigned attorney at 203-399-5900 so that appropriate arrangements can be made for resolving such issues as expeditiously as possible.

Respectfully submitted,

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